REMARKS

Claims 1-20 were examined. Applicant has amended claims 2-5, 8, 16 and 18-19. Claim 12 is cancelled. No new matter has been introduced.

Claim objections

The examiner has objected to claims 8, 16, 18 and 19. Applicants thank the examiner for the suggested amendments. Claims 8, 16, 18 and 19 have been amended.

Rejections under 35 USC §112

Claims 2-5 and 8-19 stand rejected under §112, second paragraph, as being indefinite.

Claims 2-5 and 8-19 are rejected under §112, first paragraph, as failing to comply with the written description requirement.

The claims have been overcome to overcome these grounds of rejection.

Support for items noted in paragraph 10 of the office action can be found in paragraphs [0029] – [0035], [0069]-[0071], [0073], [0078], [0093] and [0109] of the patent application

Rejections under 35 USC §103

Claims 2-3 and 5 stand rejected under §103(a) as obvious Bylund et al (2003/0212379) in view of Aceti et al (2003/0153900) in view of Sahay et al (4,442,972).

Claim 4 is rejected under §103(a) as obvious over Stevens et al (2004/0176705) in view of Aceti et al (2003/0153900) in view of Luna et al (2002/0123335).

Claims 6-7 stand rejected under §103(a) as obvious over Aceti et al (2003/0153900) in view of Britt, Jr (2001.0037355).

Claims 8-20 stand rejected under §103(a) as obvious Bylund et al (2003/0212379) in view of Aceti et al (2003/0153900) in view of Ware et al (2002/0019747).

These grounds of rejection are respectfully traversed.

The USPTO recently trained and issued guidelines for examiners relative to 35 .S.C. § 103 rejections in view of *KSR International Co. v. Teleflex Inc.*.

Examiners must account for all claim limitations in a rejections. The Examiner admits that Klump et al. does not disclose selection of geographic areas as rubber-banding or lassoing or dynamically creating dashboard displays from the selected geographic areas, where the dashboard is saveable and recallable and refreshed with live data; the dashboard allowing an operator to select information that is relevant to a situation that the operator is facing.

Examiners must either indicate how each limitation is shown by the reference(s) applied, or provide an explanation.

In general post-KSR, obviousness determinations are based upon the predictability of the invention and whether the ordinary artisan would have a reasonable expectation of successfully arriving at the claimed invention based upon the teachings of the cited references.

Exam Guideline A: Combinations

A. Combining prior art elements according to known methods to yield predictable results.
    1. The prior art includes each element as claimed, although not in a single reference.
    2. One of ordinary skill in the art could have combined the elements as claimed by known methods & in combination, each element would have performed the same function as it did separately.
    3. One of ordinary skill in the art would have recognized that the results of the combination were predictable.
    4. *Graham* factors.

The first examination guideline addresses rejections where elements from one or more references are combined to arrive at the claimed invention.

The Examination Guidelines provide that a reason should be articulated as to why the ordinary artisan would combine the elements in the way that the claimed new invention does.

Combining a collection of old elements into a single device is not obvious if the art teaches away from doing so.

The Examiner has failed, with the cited references, to provide, (i) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods and that in combination, each element merely would have performed the same function as it did separately; and (ii) a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable.

One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988); *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992).

Even where a general method that could have been applied to make the claimed product was known and within the skill level of the ordinary artisan, the claim may nonetheless be nonobvious if the problem which had suggested use of the method had been previously unknown. *In re Omeprazole Patent Litigation*, 536 F.3d 1361 (Fed. Cir. 2008). the district coutt and federal circuit found the patent nonobvious because the problem that the invention

addressed was not previously known so there was no reason for one of skill in the art to add the enteric layer.

A claimed combination of prior art elements may be nonobvious where the prior art teaches away from the claimed combination and the combination yields no more than predictable results. *Crocs, Inc. v. U.S. International Trade Commission,* 598 F.3d 1294 (Fed. Cir. 2010).

Exam Guideline B: Substitution

B. Simple substitution of one known element for another to obtain predictable results.
    1. The prior art contained a device (method, product, etc.), which differed from the claimed device by the substitution of some components (step, element, etc.) with other components.
    2. The substituted components & their functions were known in the art.
    3. One of ordinary skill in the art could have substituted one known element for another and the results of the substitution would have been predictable.
    4. *Graham* factors.

The second examination guideline addresses rejections where an element from a secondary reference is substituted into the teaching from the primary reference.

The Examination Guidelines provide that at least the primary reference should suggest that the modification could be successful.

Even in an unpredictable field, a reasonable expectation of success may justify the rejection.

The Examiner has failed, with the cited references, to provide: (i) a finding that the prior art contained a device which differed from the claimed device the substitution of some components with other components; (ii) a finding that the substituted components and their functions were known in the art; and (iii) a finding that one of ordinary skill in the art could have substituted one known element for another and the results of the substitution would have been predictable.

It is impermissible to engage in a hindsight reconstruction of the claimed invention by using the applicant's structure as a template and selecting elements from references to fill in the gaps. *In re Gorman*, 933 F.2d 892 (Fed. Cir. 1991).

A claimed compound would not have obvious where there was no reason to modify the closest prior art lead compound to obtain the claimed compound and the prior art taught that modifying the lead compound would destroy its advantageous property. Any known compound may serve as a lead compound when there is some reason for starting with that lead compound and modifying it to obtain the claimed compound. *Eisai Co. Ltd. v. Dr. Reddy's Labs* (Fed. Cir.

2008). The Fed. Cir. found that despite the structural similarities, there was no reason to modify the lead compound; a skilled artisan would have expected that replacing the trifluoroethoxy substituent with a methoxypropoxy substituent would reduce the lipophilicity of the compound.

Exam Guideline C: Skill Level

C. Use of known technique to improve similar devices (methods, or products) in the same way.
    1. The prior art contained a "base" device (method, or product) upon which the claimed invention can be seen as an "improvement."
    2. The prior art contained a "comparable" device (method, or product that is not the same as the base device) that was improved in the same way as the claimed invention.
    3. One of ordinary skill in the art could have applied the known "improvement" technique in the same way to the "base" device (method, or product) and the results would have been predictable to one of ordinary skill in the art.
    4. *Graham* factors.

The third examination guideline addresses rejections where the improvement relating to the invention is within the skill level of the ordinary artisan.

The Examination Guidelines provide that if the application of the technique is beyond the skill level of the ordinary artisan then the technique is not obvious.

The **Examiner has failed, with the cited references, to articulate the following:** (i) a finding that the prior art contained a "base" device upon which the claimed invention is an improvement; (ii) a finding that the prior art contained a comparable device that was improved in the same way as the claimed invention; and (iii) a finding that one of ordinary skill could have applied the known "improvement" technique in the same way to the "base" device and the results would have been predictable.

Factors pertinent to the level of skill element of the *Graham* obviousness analysis include (1) educational level of the inventor, (2) type of problems encountered in the art, (3) prior art solutions to those problems, (4) rapidity with which innovations are made, (5) sophistication of the technology, and (6) education level of workers active in the field. *Environmental Design, Ltd. v. Union Oil Co. of Calif.*, 713 F2d 693 (Fed. Cir. 1983). A person of ordinary skill in the art is "one who thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate..." *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448 (Fed. Cir. 1985). "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR*, 550 U.S. 398, 421 (2007).

Exam Guideline D: Common Knowledge

D. Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results.

1. The prior art contained a "base" device (method, or product) upon which the claimed invention can be seen as an "improvement."
2. The prior art contained a "known technique" that is applicable to the base device (method, or product).
3. One of ordinary skill in the art would have recognized that applying the known technique would have yielded predictable results and resulted in an improved system.
4. *Graham* factors.

The fourth examination guideline addresses rejections where the Examiner has the opportunity to apply common knowledge to the rejection.

The Examination Guidelines provide that a claim is obvious if a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art.

The Examiner has failed, with the cited references, to articulate the following: (i) a finding that the prior art contained a "base" device; (ii) a finding that the prior art contained a known technique that is applicable to the base device; and (iii) a finding that one of ordinary skill in the art would have recognized that applying the known technique would have yielded predictable results.

Where an Examiner chooses to take notice of facts beyond the record for the *prima facie* case, those facts must be "capable of such instant and unquestionable demonstration as to defy dispute." *In re Alhert*, 424 F.2d 1088, 1091 (CCPA 1970). It is ***not*** appropriate for an Examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well-known are not capable of *instant and unquestionable demonstration as being well-known. Id.* For example, assertions of technical facts in esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art. *Id.*; *see also*, MPEP § 2144.03, 8th ed., Aug. 2001, Rev. Feb. 2003, pp. 2100-131-2100-132; *In re Grose*, 592 F.2d 1161, 1167-1168 (CCPA 1979) ("[W]hen the PTO seeks to rely upon a chemical theory, in establishing a prima facie case of obviousness, it must provide evidentiary support for the existence and meaning of the theory.").

Exam Guideline E: Obvious to Try

E. "Obvious to Try" - Choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success.

1. At the time of the invention, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem.
2. There had been a finite number of identified, predictable potential solutions to the recognized need or problem.
3. One of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success.
4. *Graham* factors.

The fifth "obvious to try" examination guideline addresses another rejection where the Examiner has the opportunity to apply common knowledge to the rejection.

The Examination Guidelines emphasize that the unpredictability of a procedure may be obviated when there are only a "finite" number of solutions to solve a problem and the testing of the solutions is within the skill level of the ordinary artisan.

The **Examiner has failed, with the cited references, to articulate the following:** (i) a finding that there had been a recognized problem or need in the art including a design need or market pressure to solve a problem; (ii) a finding that there had been a finite number of identified predictable potential solutions; and (iii) a finding that one of ordinary skill in the art could have pursued the known potential options with a reasonable expectation of success.

Rolls-Royce, PLC v. United Technologies Corp., 603 F.3d 1325 (Fed. Cir. 2010). An obvious to try rationale may be proper when the possible options for solving a problem were known and finite; however, if the possible options were not either known or finite, then an obvious to try rationale cannot be used to support a conclusion of obviousness.

Exam Guideline F: Analogous Elements

F. Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art.
    1. The scope and content of the prior art, whether in the same field of endeavor as that of the applicant's invention or a different field of endeavor, included a similar or analogous device (method, or product).
    2. There were design incentives or market forces that would have prompted adaptation of the known device (method, or product).
    3. The differences between the claimed invention and the prior art were encompassed in known variations or in a principle known in the art.
    4. One of ordinary skill in the art, in view of the identified design incentives or other market forces, could have implemented the claimed variation of the prior art, and

the claimed variation would have been predictable to one of ordinary skill in the art.

5. *Graham* factors.

The sixth examination guideline includes rejections that cite non-analogous art.

The Examination Guidelines cite Leapfrog & KSR as a representative of rejections brought under this Guideline. Leapfrog combined electrical & mechanical elements to arrive at the claimed electronic toy. KSR combined two mechanical elements to arrive at the claimed adjustable pedal assembly.

The Examiner has failed, with the cited references, to articulate the following: (i) a finding that the scope and content of the prior art, whether in the same or different field of endeavor, included a similar or analogous device; (ii) a finding that there were design incentives or market forces which would have prompted adaptation of the known device; (iii) a finding that the differences between the claimed invention and the prior art were encompassed in known variations or in a principle known in the prior art; and (iv) a finding that one of ordinary skill in the art, in view of the design incentives or market forces, could have implemented the claimed variation of the prior art, and the claimed variation would have been predictable.

The combination of elements from non-analogous sources, in a manner that reconstructs the applicants invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

Exam Guideline G: TSM

G. Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention (TSM).

   1. There was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings.
   2. There was a reasonable expectation of success.
   3. *Graham* factors.

The seventh examination guideline addresses rejections that use the TSM test.

A retrospective view of inherency is not a substitute for some teaching or suggestion that supports the selection and use of the various elements in the particular claimed combination. *In re Newell*, 891 F.2d 899 (Fed. Cir. 1989).

Both the suggestion and the reasonable expectation of success "must be founded in the prior art, not in the applicant's disclosure." *In re Vaeck*, 947 F.2d 488, 473 (Fed. Cir. 1991).

The Court of Appeals for the Federal Circuit has explained that the rationale to support a conclusion that a claim would have been obvious is that "a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success." USPTO Examination Guidelines, 72 Fed. Reg. 195 (2007) *quoting DyStar Textilfarben GmbH & Co. Deutschland KG* v. *C.H. Patrick Co.,* 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006).

A showing of obviousness requires a motivation or suggestion to combine or modify prior art references, coupled with a reasonable expectation of success..."While absolute certainty is not necessary to establish a reasonable expectation of success, [citations omitted] there can be little better evidence negating an expectation of success than actual reports of failure." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339 (Fed. Cir. 2003).

It is well-established that an obviousness analysis that relies upon the applicant's disclosure rather than the prior art reference is improper as being based upon an impermissible hindsight reconstruction. *In re Deuel,* 51 F.3d 1551, 1558 (Fed. Cir. 1995).

A single line in a prior art reference should not be taken out of context and relied upon with the benefit of hindsight. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443 (Fed. Cir. 1986).

Using the inventor's success as evidence that one or ordinary skill in the art would have reasonably expected success represents an impermissible use of hindsight. *Life Technologies, Inc. v. Clontech Laboratories, Inc.*, 224 F.3d 1320 (Fed. Cir. 2000).

"The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time." *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138 (Fed. Cir. 1985).

The Examiner has not meet the Examination guidelines established by the Patent Office, and recited above.

In one embodiment of the present invention, as set forth in claim 2, an analyte measurement device is provided that includes, a housing, a plurality of penetrating members positionable in the housing and a penetrating member driver configured to be coupled to penetrating members. A visual display is on the housing. The visual display has at least one visual indicator positioned next to a corresponding marking on the housing. A processor drives the visual display and runs software that is modifiable to provide a variable user interface on the

visual display. The processor includes instructions for controlling the penetrating member driver and for determining that a penetrating member has contacted a skin surface.

None of the cited references, singularly or in combination provide a processor, (i) that drives a visual display and runs software which is modifiable to provide a variable user interface on the visual display and (ii) with instructions for controlling a penetrating member driver and determine that a penetrating member has contacted a skin surface.

Aceti et al. discloses an analyte monitoring/drug (pharmaceutical agent) delivery device with a housing that at least partially encloses a plurality of microneedles disposed on a carrier and an electronics portion. The microneedles are in fluid communication with a corresponding microchannel. The microneedles can be extended and retracted individually with an actuator. An electronics portion is provided that includes a processor and associated circuitry.

The processor of Aceti et al. does not have instructions for both controlling the actuator and also determines when the microneedle has contacted a skin surface.

In operation, a single microneedle is moved into the extended position and penetrates the skin. The microneedle penetrates through the skin. The processor does not know when the microneedle has touched the skin. Instead, the actuator drives the microneedle through the skin, but does not determine when the microneedle has made contact with the skin surface.

Ware et al. discloses a system of multiple modules or processes, such as test generation, testing or administering, evaluating and reporting.

The only discussion of a processor is a handheld computer with a central processor unit that is a device in the system.

In the test generation process or module, the system collects data from a pre-existing data pool or database of questions and answers, statistically assesses the data, and forms a test for subsequent use in the testing process and process (or administration and evaluation modules).

The system collects data by generating a survey of questions with a list of possible answers and providing it to one or more survey respondents in order to elicit their responses thereto. The individual questions of the survey are the same as the tests to be subsequently utilized in testing and evaluation. The survey includes one or more questions related to each of one or more domains which are sought to be evaluated by an assessment method.

Sahay et al. is in an entirely different technology, namely thermostats. Sahay et al. does not disclose, suggest, or infer, (i) a processor with instructions for controlling a penetrating member driver that also determines that a penetrating member has contacted a skin surface, (ii) an analyte measurement device with a housing, a plurality of penetrating members positionable

in the housing and a penetrating member driver configured to be coupled to penetrating members, (iii) a visual display on the housing with at least one visual indicator positioned next to a corresponding marking on the housing and (iv) a processor that drives the visual display and runs software that is modifiable to provide a variable user interface on the visual display.

Sahay et al. discloses an electronically controlled programmable wall thermostat. The thermostat includes a clock, temperature sensor, means for displaying desired parameters of time and temperature, data entry and storage means for programming the thermostat to maintain desired temperatures during selected time intervals, and a processing means with a memory incorporating a permanently stored program instruction sequence which responds to signals from the temperature sensing means for controlling the heating and cooling systems in accordance with the time-temperature sequence programmed into the thermostat by the user.

Stevens et al. discloses a system for collecting a fluid sample into a sealed cartridge that includes an integrated sample collection mechanism having a shielded piercing element such as a syringe or lancet assembly which is capable of collecting a fluid sample into a containment chamber. The chamber includes an array of electrical contacts, electrochemical sensors and circuitry configured to electrically couple with a hand-held analytical device such as a personal digital assistant (PDA), which controls the testing of the fluid sample within the cartridge and provides a rapid indication of test results.

Stevens et al. does not provide or suggest, (i) a processor with instructions for controlling a penetrating member driver that also determines that a penetrating member has contacted a skin surface, (ii) an analyte measurement device with a housing, a plurality of penetrating members positionable in the housing and a penetrating member driver configured to be coupled to penetrating members, (iii) a visual display on the housing with at least one visual indicator positioned next to a corresponding marking on the housing and (iv) a processor that drives the visual display and runs software that is modifiable to provide a variable user interface on the visual display.

Luna et al. also does not have the processor and the elements set forth in claim 2 above. Luna et al. discloses an apparatus for provisioning a mobile station over a wireless network.

Bylund et al. does not disclose, suggest, or infer, (i) a processor with instructions for controlling a penetrating member driver that also determines that a penetrating member has contacted a skin surface, (ii) an analyte measurement device with a housing, a plurality of penetrating members positionable in the housing and a penetrating member driver configured to be coupled to penetrating members, (iii) a visual display on the housing with at least one visual

indicator positioned next to a corresponding marking on the housing and (iv) a processor that drives the visual display and runs software that is modifiable to provide a variable user interface on the visual display.

Instead, Bylund et al. is an infusion system that has a medication infusion pump worn on the body of a patient. A physiological fluid monitoring device is also worn on the body of the patient for continuous monitoring of at least one characteristic of a physiological fluid. A remote control device remotely controls the medication infusion pump and the physiological fluid monitoring device, wherein the remote control device comprises a physiological fluid monitoring means for the episodic monitoring of at least one characteristic of physiological fluid.

Britt Jr. discloses an apparatus for announcing a transmission from a caller by vibrating in a predetermined manner associated with the caller. Also disclosed is a method comprising: receiving a transmission from a first caller; identifying the first caller; and vibrating a device in a predetermined manner based on said first caller's identity.

CONCLUSION

Applicants submit this to put the application in condition for allowance.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. **50-4634**, referencing attorney's docket no. **PEL 2840.**

Respectfully submitted,

Date: 1/24/11

By: _____
Paul Davis, Reg. No. 29,294

GOODWIN PROCTER LLP
135 Commonwealth Drive
Menlo Park, CA 94025
Telephone:
650/752-3106
Customer No. 77845